Public Testimony of Lillian Thiemann, research workgroup co-chair of the Women's HIV Collaborative of New York and co-founder and president of Visionary Health Concepts, a community-driven medical education company specializing in HIV and hepatitis.

Speaker Background: Ms. Thiemann was diagnosed with HIV and hepatitis C in 1989 and is a former intravenous drug user. She achieved national recognition with her column "Dope Fiends Corner" for POZ magazine. The popular patient and secondary provider programs she has written and designed including "Double Jeopardy: the HIV/HCV Co-Infection Handbook" and "The Future of HIV Treatment." Her newest education programs are targeted to physicians and include the CME-accredited monograph, "Explorations in Care:Metabolic Abnormalities in HIV" and "Vital Lines: Management of Clinical Challenges in HIV/HCV Co-Infection." She has been a participant in the New York University cohort of the ACTG-O35 study for 8 years.

Public Statement: A Perspective on the Relevance of Women's Health Research

I am an HIV-positive woman from New York City, and I am here to give you my experience with clinical trials in HIV and to talk to you about their comparative relevance in the pre- and post-HAART eras. (For those of you not working in the HIV field, "HAART" is "highly active anti-retroviral therapy.")

Relevance was a much clearer issue in the pre-HAART era than it is today. I was a member of the People With AIDS (PWA) Health Group, and was referred there through my case manager at a drug treatment program because I really wanted to attend a group that talked about HIV treatment and women. There was nothing like that happening anywhere except at the People With Aids Health Group. I joined the Women's Treatment Project where a continual parade of MDs, RNs, dietitians, and AIDS activists would talk to a diverse group of about 12 women, some fresh out of prison and some women who, like me, knew nothing about HIV. Most researchers did not know much about HIV at that time, either.

The PWA Health Group tried its best to answer some of the problems of AIDS by importing drugs from other countries that were not yet approved in the United States. They accomplished this with the help of physicians in the United States who would write prescriptions for these agents so that people who represented our group could travel to other countries and obtain the treatments and bring them back into the US. We did this so that people who were suffering with opportunistic infections and side effects of the approved AIDS drugs could get some relief from those side effects.

In 1995, six years after my HIV diagnosis, Phase III trials for protease inhibitors began enrolling research participants (Roche Labs' Saquinavir and Merck's Indinavir trials). At that time, if you wanted to participate in a protease inhibitor trial you put your name in a lottery; thousands of people entered their names (or their doctors did), and names were literally picked out of a hat. For the Indinavir trials, a waiting list was compiled.

So when, at the behest of my health care provider, I called the AIDS Clinical Trial Group (ACTG) at New York University to request enrollment in the Indinavir trial, I had five T-cells

and a very high HIV viral load and, although I had never suffered a major opportunistic infection (just minor ones like thrush), the researchers and I both knew that I was on the skids and starting to "circle the drain." So I called the study nurse and requested to enroll in the trial. Her response was, "I'm really sorry, but it's fully enrolled." Not to be deterred, I asked if my name could be put on a waiting list. Her response was, "Sure; you are number 2,347." It was a major psychological setback to hear that number, but I really needed to participate in that trial so I told her what a fabulous study participant I would be: "I will show up for every appointment, take every test, and stick with it to the very end." She said, "That's very nice, but you're still number 2,347."

I called her the following week and the week after that; I think I called her twice a week for a month or so. By the fifth or sixth time I called, I only had to say hello and she would recognize my voice; she would say, "Hello, Lillian; you're still number 2,347. Thank you for calling." Finally, I think I had tortured her enough because she said, "Listen, Lillian, I understand you would be a great study participant, that you'll come to every appointment, take every drug, do every test, stick with it to the end. I have that, but please stop calling." It was difficult for her every time she had to talk to me. I would like to think that I was not begging but I am sure that there was an edge in my voice that was slightly like that.

As time went on, I did stop calling and I accepted the fact that I was going to get sick and die, like many of the people I watched around me. Acceptance is a beautiful thing. Two weeks later my phone rang and I heard a woman's voice with a Filipino accent, asking for me; it was Candy, the study nurse. (Her name is Candida, and for those of you who work in HIV it is an inside joke.) She said, "Lillian, are you still interested in being in the trial?" I said I was. She said, "We've had many dropouts. The drugs have side effects. We had a meeting and we were discussing who could we get who would show up for every appointment, who would take every drug, and who would hang in until the end. And, magically, your name popped into my head!"

Well, I have been a participant in the ACTGO35 study for almost 8 years. Every year, for my work, I go to the Conference of Retroviruses and Opportunistic Infections to listen to the latest data and to get ideas for educational programs. Every time, although it is old hat now, Trip Gulick, the primary investigator for ACTGO35, trots out the latest data. I sit there and I am proud to hear that data.

When I first entered the study, it was extremely relevant for me because I believed I was going to die. As time went on and more drugs became approved, many people were exiting the trial that I was on, but I wanted to stay because it was still relevant to me – I received very good health care on my clinical trial. They looked at me very closely and we formed a relationship over time that was very important to me. As time went on, the relevance as far as getting free drugs was no longer there. At the time I was on Medicaid, and I could get anything that was approved in the United States. Yet the longer I was on the trial and the longer I consorted with HIV treatment activists, the more I knew how extremely important it was for women to be enrolled in clinical trials. I wanted that long-term data to be available; even if not enough women were in my particular cohort to make it statistically significant, I felt that some really important data might come out over time. I stayed, on a dinosaur of a regimen; HIV drug regimens are not like that anymore and the trial is now being stopped.

What I now understand through my membership at the Women's HIV Collaborative of New York is that activists did a really wonderful job, with the help of well-placed medical activists in the NIH and other agencies in the United States forcing the issue, so that the restrictions on women in clinical trials and the exclusion of women from clinical trials would go away. For the most part, women are now welcomed in trials in which they can enroll. However, women are not showing up. It is not news that women and men are different, and we must all understand that we need to tell the clinical trial story from the "female experience" point of view.

This year when I heard that this conference was going to occur I took time out of my schedule because I felt it was so important to have a presence here and to see what you all are doing. I also want to find out about other disease states and, for the people who are still working in HIV, where we can make a difference. I want to gather information here to do what I do best, which is produce educational programs to help healthcare providers and patients learn what they need to in order to move along a continuum that brings everyone's health up a notch.

I hope I can generate some interest in producing education based on the knowledge that I gain here from all of you, and I thank you for your kind attention and for all your work.